REMARKS/ARGUMENTS

The Status of the Claims.

Claims 1-25 are currently pending. Applicants have provisionally elected group I (claims 1-3, 5-12 and 14-23) for initial examination per 37 CFR §1.143.

Election/Restriction Requirement.

The Office alleges that the above-identified application contains multiple inventions or groups of invention that are not linked so as to form a single general inventive concept under PCT Rule 13.1. The Examiner has subsequently restricted claims 1-25 of the application into four groups: Group I, claims 1-3, 5-12 and 14-23 (methods of aiding in renal cell carcinoma to the extent that the quantified species is a polypeptide); Group II, claims 1, 3-4 and 6-13 (methods of aiding in renal cell carcinoma to the extent that the quantified species is a polynucleotide); Group III, claims 24-25 (computer program products to the extent that the expression data comprises CAIX polypeptide sequences); and Group IV, claims 24-25 (computer program products to the extent that the expression data comprises CAIX polynucleotide sequences).

Request for clarification regarding division of claims

Given that the Examiner has indicated that the claims have been restriction "to the extent the CAIX quantified" is either a polypeptide or polynucleotide, Applicants respectfully suggest that the Examiner may have meant the following claims to have been included in Groups I and II:

> Group I: claims 1-3, 5-13 and 14-23 (including claim 13, which is drawn to computer program embodiment applicable to either peptide or nucleotide embodiments)
>
> Group II: claims 1-2, 4, and 6-13 (but not claim 3, which is drawn to peptide embodiment)

Should the restriction be maintained, Applicants request clarification with respect to the claims included in each group.

Summary of Traversal

Applicants traverse on the grounds that the restriction is improper. First, by restricting a single claim into multiple groups, the Office is attempting to force Applicants to

amend the claims under 35 U.S.C. §121, which is improper. Second, the Office is incorrect in restricting the computer program product claims away from the prognosis method claims. And finally, the art cited as a rational for alleging that the claims lack a special technical feature is improper: the cited publication does not teach or disclose the claimed methods and computer program products related to prognosis of renal cell carcinoma. Applicants has addressed each of these issues in more detail below.

35 USC § 121 DOES NOT PROVIDE A BASIS TO *REJECT* A CLAIM FOR "MISJOINDER" OR LACK OF UNITY

Claim 1, which is included in both Groups I and II, is drawn to methods of aiding in a renal cell carcinoma prognosis. In brief, the claimed methods include the steps of (a) quantifying expressed carbonic anhydrase IX (CAIX) in one or more samples to produce quantified CAIX expression data; and, (b) correlating the quantified CAIX expression data with a probability of a renal cell carcinoma prognosis for the subject. Dependent claim 3 (which is included in both Groups I and II) is drawn to embodiments in which the expressed CAIX comprises a CAIX polypeptide or fragment thereof. Dependent claim 4 (which is include only in Group II) is drawn to embodiments in which the expressed CAIX comprises a messenger RNA that encodes a CAIX polypeptide. Independent claim 24 is drawn to computer program products including, but not limited to, logic instructions for receiving quantified CAIX expression data; while no limitation with respect to polynucleotide vs. polypeptide sequence has been presented in a dependent claim, these claims have also been restricted into Groups III and IV based upon such presumption.

Applicants have a constitutional and statutory right to have their invention examined and the Office as an administrative body is bound to recognize these rights. By restricting claim embodiments involving CAIX polypeptide sequences from embodiments related to CAIX polynucleotide sequences, the Office is requiring that independent claims 1 and 24 be amended to incorporate such limitations. Applicants note that **the Office flatly lacks the authority to use 35 U.S.C. § 121 as a basis for forcing amendment of a claim**. All case law addressing the issue of restricting a claim into parts away from itself, as the Rejection requires for the subject claims, makes this perfectly clear. The Courts have repeatedly stated that the divisional statute provides no basis at all for the separation of claim

elements within a single claim, as the Office has here required (i.e., restricting the case to either polypeptide sequences or polynucleotide sequences). As the Courts have noted:

> As a general proposition, an applicant has a right to have each claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not affect the rights of the applicant eventually to have each of the claims examined in the form he considers to best define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on the merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner, rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification.

See, In Re Weber, Soder and Boksay 198 USPQ 328, 331 (C.C.P.A. 1978). *See also, In Re Haas* 179 USPQ 623, 624, 625 (*In Re Haas I*) (C.C.P.A. 1973) and *In Re Haas* 198 USPQ 334-337 (*In Re Haas II*) (C.C.P.A. 1978).

Thus, it has long been held that the Office simply may not restrict a particular claim on the basis that it claims independent and distinct inventions. The courts have definitively ruled that the statute authorizing restriction practice, *i.e.*, 35 U.S.C. §121, provides no legal authority to impose a restriction requirement on a single claim, even if the claim presents multiple independently patentable inventions. In the cases set forth above, **the courts expressly ruled that there is no statutory basis for rejecting a claim for "misjoinder" (rejection for inclusion of multiple independent inventions within a claim)** despite previous attempts by the Patent Office to fashion such a rejection. For example, *In re Webber* (198 USPQ 328) sets forth the following (*see*, 331-332):

> It is apparent that §121 provides the commissioner with the authority to promulgate rules designed to restrict an application to one of several claimed inventions when those inventions are found to be "independent and distinct." It does not, however, provide a basis for an examiner, acting under the authority of the commissioner to reject a particular claim on the same basis.

In re Haas (198 USPQ 335) interprets this as a *per se* holding, in the very next case by the court:

> In *In re Weber...* decided of even date, this court holds that § 121 does not provide a basis for rejection of a claim. To the extent that § 121 was employed as a basis for rejection, that rejection is, on the authority of Weber, reversed.

As the Courts have repeatedly and pointedly indicated, the Office simply may not refuse to examine a claim, no matter how many inventions it allegedly embraces. Applicants respectfully submit that the embodiments related to CAIX polypeptide sequences (Groups I and III) should not be restricted away from the embodiments related to CAIX polynucleotide sequences (Group II and IV), and respectfully request that the Groups I and II be rejoined, and Groups II and IV be rejoined.

UNITY OF INVENTION UNDER PCT RULE 13.1

PCT Rule 13.1 states "The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ('requirement of unity of invention')." The Patent Cooperation Treaty goes on to state "Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art."

Improper restriction of process and an apparatus specifically designed for carrying out the said process

The Examiner has cited 37 CFR §1.449 as providing the authority to require Applicant to elect the invention to which the claims shall be restricted, should the national stage application lacks unity of invention under § 1.475. Applicants note that 37 CFR 1.475(b) also specifies that

> (b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:
>
> (1) A product and a process specially adapted for the manufacture of said product; or

> (2) A product and process of use of said product; or
>
> (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
>
> **(4) A process and an apparatus or means specifically designed for carrying out the said process; or**
>
> (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

(emphasis added). The claims presented by Applicant are drawn to methods of aiding in renal cell carcinoma prognosis, and computer program products for performing such prognosis methods. Applicants respectfully submit that the computer product claims should not be restricted away from the method claims, and respectfully request that the Groups III and IV be rejoined with Groups I and II, respectively.

Special Technical Feature

The Examiner has stated that Groups I through IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under Rule 1.2, the claims purportedly lack a common special technical feature. The claimed methods are allegedly disclosed in Ivanov et al. (2001) Am. J. Pathology 158:905-919. Applicants note unity of invention was not disputed in the International Search Report mailed 28 August 2003(prepared by the same Examiner), and the publication cited by the Office was categorized as an "A" document (i.e., defining the general state of the art which is not considered to be of particular relevance).

Applicants traverse this finding; the cited art does not teach or describe the invention claimed in the subject application. Ivanov is directed to expression of hypoxia-induced cell surface carbonic anhydrases (e.g., CAIX and CAXII) in human cancers. As noted in the header at page 910, column 2 (and elsewhere in the publication), expression of CAIX and CA XII are diagnostic for renal cell carcinomas. The Examiner has pointed to Table 4 on page 913 of the cited publication, which provides correlations, if any, between anhydrase expression and tumor diagnosis (benign vs. malignant). In contrast, Applicant is claiming methods and computer program products for aiding in a renal cell carcinoma prognosis. Applicants emphasize that "prognosis" (the forecast as to the probable outcome of

a disease state and prospect as to recovery; see definition in paragraph [0033] on page 12 of the specification) is not the same as "diagnosis" (i.e., determination whether the disease is present). Ivanov is only directed to diagnosis of disease, and is mute with respect to prognosis of disease progression.

Given that the cited publication does not teach the special technical features recited in the claimed invention, Applicants submit that the restriction of the claims as allegedly not linked to form a single general concept based upon this publication is improper.

REQUEST FOR EXAMINER INTERVIEW

For the reasons noted above, the restriction requirement is improper and should be withdrawn.

In the event that the restriction is maintained in its current form, **Applicants hereby request an interview with the Examiner and the Examiner's SPE to discuss the subject restriction requirement PRIOR TO ANY ACTION ON THE MERITS.**

CONCLUSION

In view of the foregoing, Applicants believes all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the claims are deemed not to be in condition for allowance after consideration of this Response, a telephone interview with the Examiner is hereby requested. Please telephone the undersigned at (510) 337-7871 to schedule an interview.

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Respectfully submitted,

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Attachments:

1) A petition to extend the period of response for **3** months;
2) A transmittal sheet;
3) A fee transmittal sheet; and,
4) A receipt indication postcard.